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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/512,731	10/26/2004	Daniel W. Chan	57222(71699)	1716
49383 7590 10/01/2009 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 POSTON, MA 02205			EXAMINER	
			RAWLINGS, STEPHEN L	
BOSTON, MA 02205			ART UNIT	PAPER NUMBER
			1643	
			MAIL DATE	DELIVERY MODE
			10/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of Non-Responsive Amendment

1. The amendment filed June 4, 2009, is non-responsive for the following reasons:

The amendment filed June 4, 2009, would amend all claims, which were previously drawn to the elected invention, so as to present only claims drawn to a non-elected invention.

The claims, as would be amended, are not readable on the elected invention for the following reasons:

As would be amended, claims 1-4, 11, and 12 would be directed to a method comprising determining that a subject <u>has</u> prostate cancer if there is a decrease in the amount of a marker as compared to a control (i.e., a method of determining if a subject has prostate cancer).

However, Applicant has elected without traverse the invention of Group III, claim 5, drawn to a method of qualifying prostate cancer status in a subject, said method comprising measuring at least one biomarker in a sample from the subject, wherein said prostate cancer status is **the type of disease**.

In keeping with the nature of the elected invention, it is submitted that claim 1 should be amended to recite a positive correlation between the level of the marker in the sample from the subject and *the type of prostate cancer* in the subject - not the presence of the disease.

As stated previously in the Office communication mailed July 29, 2008, qualifying *the type of disease* is not the same as determining if a subject has the disease.

The presence or absence of the disease does not provide an indication of the type of the disease.

It is further submitted that a process for determining if a subject has prostate cancer, if not a wholly different invention from those to which the originally presented claims were directed, *might fall within the scope of claims directed to the non-elected invention of Group II*, which as in accordance with the restriction and election nrequirement set forth in the Office action mailed March 27, 2007, is a method of qualifying prostate cancer status in a subject, said method comprising measuring at

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least one biomarker in a sample from the subject, wherein said prostate cancer status is the presence or absence of disease.

Because the breadth of claims 1-4, 11, and 12, as the claims would be amended, differs so substantially from the breath of the originally present claims, which were directed to the elected invention, examination of the amended claims would require new and different considerations and searches, which were not before necessary. As such, examination of the claims, as would be amended, would be unduly burdensome.

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Accordingly, after entry of the amendment, all remaining claims would be withdrawn from consideration as being directed to non-elected inventions, and therefore the amendment, which presents only claims drawn to such non-elected inventions, is non-responsive. See 37 CFR 1.142(b) and MPEP § 821.03.

- 2. Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).
- 3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stephen L. Rawlings/ Primary Examiner, Art Unit 1643

slr September 30, 2009